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DOCKET NO.: C1005.70011US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Pykett et al.

Serial No.:

10/705,720

Confirmation No.: Filed:

Not Yet Assigned

rne

November 10, 2003

For:

METHODS AND DEVICES FOR THE LONG-TERM CULTURE OF

HEMATOPOIETIC PROGENITOR CELLS

Examiner:

Not Yet Assigned

Art Unit:

Not Yet Assigned

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the day of April, 2004.

Kristin I Ketellist

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- [X] Information Disclosure Statement
- [X] PTO Form 1449 with cited references
- [X] Copy of International Search Report dated February 16, 1999
- [X] Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Pykett et al., Applicant

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Docket No. C1005.70011US00

Date: April $\frac{10}{4}$, 2004

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application. The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| Docket No. | Serial No. | Filing Date | Inventor(s) |
|-----------------|------------|-------------|---------------|
| C1005.70008US00 | 10/088,826 | 8/13/2002 | Pykett et al. |
| C1005.70009US00 | 10/088,825 | 8/30/2002 | Upton et al. |
| C1005.70012US00 | 10/161,097 | 5/31/2002 | Pykett et al. |

The Applicant would like to bring to the Examiner's attention the enclosed Search Report or other communication from a corresponding International or Foreign National Application.

| Docket No. | Serial No. | Publication Date | Type of Publication |
|-----------------|----------------|-------------------|---|
| C1005.70000WO00 | PCT/US98/20123 | 16 February 1999 | International Search Report |
| C1005.70000WO00 | PCT/US98/20123 | 20 September 1999 | Written Opinion |
| C1005.70000WO00 | PCT/US98/20123 | 10 February 2000 | International Preliminary Examination Report |

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Mark J. Pykett et al., *Applicant*

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Docket No. C1005.70011US01

Date: April [6], 2004

XNDDX

FORM PTO-1449/A and B (Modified)

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APR 2 1 2004

APPLICATION NO.: 10/705,720

ATTY. DOCKET NO.: C1005.70011US01

FILING DATE:

November 10, 2003

CONFIRMATION NO.: Not yet assigned

APPLICANT:

Mark J. Pykett et al.

GROUP ART UNIT: Not yet assigned

EXAMINER:

Not yet assigned

U.S. PATENT DOCUMENTS

| Examiner's | Cite | U.S. Patent Do | cument | Name of Patentee or Applicant of Cited | Date of Publication or of issue of Cited Document MM-DD-YYYY | |
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| Initials | No. | Number | Kind Code | Document | | |
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FOREIGN PATENT DOCUMENTS

| Examiner's | Cite | For | eign Patent Docum | ment | Name of Patentee or Applicant of Cited | Date of Publication of | Translation |
|------------|------|--------------------|-------------------|--------------|--|------------------------------------|-------------|
| Initials | No. | Office/ Country | Number | Kind Code | Document (not necessary) | y) Cited Document (Y MM-DD-YYYY | (Y/N) |
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| | B8 * | EP | 0 358 506 | | | 03/90 | |
| | B9 * | EP | 0 560 279 | A | | 09/93 | |

OTHER ART — NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
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| | C1 * | ANDERSON, et al., "MHC class II-positive epithelium and mesenchyme cells are both required for T-cell development in the thymus", <i>Nature</i> , 362, pp. 70-73 (1993). | |
| | C2 * | BAGLEY, et al., "Extended culture of multipotent hematopoietic progenitors without cytokine augmentation in a novel three-dimensional device", <i>Experimental Hematology</i> , 27(3), pp. 496-504 (1999). | |
| | C3 * | BAGLEY, et al., "Long-term three dimensional hematopoietic stem cell culture", Amer. Chem. Soc., 126(1/03). ABSTRACT ONLY | |
| | C4 * | BOBYN, et al., "Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial", <i>Journal of Bone & Joint Surgery (Br.)</i> , 81-B(5), pp. 907-914 (1999). | |
| | C5 * | BOYD, et al. "The thymic microenvironment", <i>Immunology Today</i> , 14(9), pp. 445-459 (1993). | |

| FORM PTO-1449/A and B (Modified) | APPLICATION NO.: | 10/705,720 | ATTY. DOCKET NO.: | C1005.70011US01 |
|----------------------------------|------------------|-----------------------|-------------------|------------------|
| INFORMATION DISCLOSURE | FILING DATE: | November 10, 2003 | CONFIRMATION NO.: | Not yet assigned |
| STATEMENT BY APPLICANT | APPLICANT: | Mark J. Pykett et al. | | |
| Sheet 2 g/of 2 | GROUP ART UNIT: | Not yet assigned | EXAMINER: | Not yet assigned |

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| | C6 * | CLAY, et al., "Potential use of T cell receptor genes to modify hematopoietic stem cells for the gene therapy of cancer", <i>Pathology Oncology Research</i> , 5(1), pp. 3-15 (1999). | |
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| | C8 * | GARDNER, et al., "T-lymphopoietic capacity of cord blood-derived CD34+ progenitor cells", Experimental Hematology, 26, pp. 991-999 (1998). | |
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| | C10 * | NAUGHTON, et al., "Three-dimensional culture system for the growth of hematopoietic cells", <i>Prog. Clin. Biol. Res.</i> , 333, pp. 435-445, (1990). | |
| • | C11 * | PAWELEC, et al., "Extrathymic T cell differentiation in vitro from human CD34+ stem cells", Journal of Leukocyte Biology, 64, pp. 733-739 (1998). | |
| | C12 * | PORTER, et al., "A tissue of T cells", Nature Biotechnology, 18, pp. 714-715 (2000). | |
| • | C13 * | POZNANSKY, et al., "Efficient generation of human T cells from a tissue-engineered thymic organoid", <i>Nature Biotechnology</i> , 18, pp. 729-734 (2000). | |
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| | C15 * | ROSENZWEIG, et al., "Enhanced maintenance and retroviral transduction of primitive hematopoietic progenitor cells using a novel three-dimensional culture system", <i>Gene Therapy</i> , 4(9), pages 928-936 (1997). | |
| | C16 * | ROSENZWEIG, et al., "In vitro T lymphopoiesis of human and rhesus CD34+ progenitor cells", Blood, 87(10), pp. 4040-4048 (1996). | |
| | C17 * | ROSENZWEIG, et al., "In vitro T lymphopoiesis: A model system for stem cell gene therapy for AIDS", Journal of Medical Primatology, 25, pp. 192-200 (1996). | |
| | C18 | STACKPOOL, GJ, et al., "Bone ingrowth characteristics of porous tantalum: a new material for orthopaedic implants", Combined Orthopaedic Research Societies Meeting, November 6-8, 1995, San Diego, CA, Abstract Book pg 45. | |
| | C19 | TURNER, TM, et al., "Evaluation of tantalum foam, a novel porous material, for bone ingrowth fixation using a canine model", 21 st Annual Meeting of the Society for Biomaterials, March 18-22, San Francisco, CA, Abstract Book, pg 125. | |
| | C20 * | VAN EWIJK, "T-cell differentiation is influenced by thymic microenvironments", Annual Review of Immunology, 9, pp. 591-615 (1991). | |
| | C21 * | VAN VLIET, et al., "Stromal cell types in the developing thymus of the normal and nude mouse embryo", European Journal of Immunology, 15, pp. 675-681 (1985). | |
| | C22 * | WANG, et al, "Multilineal hematopoiesis in a three-dimensional murine long-term bone marrow culture", <i>Experimental Hematology</i> , pp. 26-32, (1995). | |

| EXAMINER | DATE CONSIDERED |
|----------|-----------------|
| | |

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{*}a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. <u>10/143,540</u>, filed <u>May 10, 2002</u>, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).